

Appl. No.: 10/720,662  
Amdt. dated 3/20/2006  
Reply to Office action of 12/20/2005

### **REMARKS/ARGUMENTS**

As described below, Claim 14 has been amended to clarify the invention. Claims 9-12 and 16-18 have been cancelled, thereby leaving claims 14 and 15 as the only pending claims that have not been withdrawn. Based on the foregoing amendments and the following remarks, Applicant respectfully requests withdrawal of the rejections and formal notification of allowance for all claims currently presented.

#### ***Claim Objections***

Claims 9 and 16 were objected to because the claims read on a sequence in which one or both asparagines of the pre-S protein at amino acid "position" 15 and 123 have been replaced. Claims 9 and 16 have been cancelled thus obviating the objection.

#### ***35 U.S.C. § 112***

Claims 14-15 have been rejected under 35 U.S.C. § 112, first and second paragraphs. The Office Action asserts that the Specification does not enable one skilled in the art to make and/or use the invention related to pIL20-pre-S Vectors, and that "there is no description of the Initial pIL20 vector." As amended, Claim 14 does not recite a pIL20-pre-S Vector. Accordingly, the rejection of Claim 14 and any claims dependent thereon under 35 U.S.C. § 112, first or second paragraphs, has been overcome.

#### ***35 U.S.C. § 103(a)***

Claims 9, 11, 12 and 14-18 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the cited references. To further distinguish the claimed invention, Claim 14 has been amended to recite that the yeast transformant secretes the mutant pre-S protein encoded by SEQ ID NO's: 9-11 into culture media without linkage to S protein by amino acid substitution at positions 15 and 123 in pre-S1 protein.

In order to establish a *prima facie* case of obviousness the references must teach or suggest each and every claim limitation. It is respectfully submitted that the references cited, considered individually or in combination, fail to teach or suggest every element of the currently claimed invention. In particular, the references taken either individually or in combination fail to teach or suggest a yeast transformant that secretes the mutant pre-S without linkage to S Protein.

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Moreover, the references fail to teach or suggest such secretion by the specific amino acid substitution at positions 15 and 123, wherein the mutant pre-S protein is encoded by Seq ID NO's: 9-11.

Furthermore, in order to combine references under 35 U.S.C §103, there must be some suggestion or motivation in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the teachings. To date, the Examiner has cited and combined a myriad number of references encompassing a rather divergent scope of teachings. Specifically, the Examiner has combined teachings related to quite different subject matter such as; references directed to HBV proteins (Ellis & Kniskern), hG-CSF / hGH secretion systems (Lee & Jang), HBV genomic sequences (Takahashi) and HIV-1 proteins (Essex) have all been concomitantly combined to construct rejections under 35 U.S.C §103. To further illustrate the divergent subject matter of the cited references, it accepted knowledge that HBV and HIV are not related. HBV is a non-retrovirus, while HIV is a retrovirus. Furthermore, Hepatitis B's genome is DNA, and reverse transcription is one of the latter steps in making new viral particles, whereas HIV has an RNA genome and reverse transcription is one of the first steps in replication. The Examiner has failed to provide any basis that would suggest combining all of these references.

In rejecting a claim under 103, it is improper to pick and choose among the individual elements of assorted prior art references to recreate the claimed invention. To date, the Examiner has merely identified isolated elements from the references and combined them in an effort to reconstruct the claimed invention. What is missing is an explanation, supported by objective evidence of why one of ordinary skill in the art would be motivated to combine so many divergent references. Additionally, the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. Clearly, the references themselves contain no specific teachings that would incite someone to combine all of the cited references in the manner that the Examiner has asserted. Moreover, Applicant has shown that a person of ordinary skill in the art would not, either from the references or from the knowledge generally available to one of ordinary skill, be motivated to make these combinations. From the foregoing, it should be

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evident that hindsight reliance upon applicant's own disclosure is the only conceivable basis why one would combine Ellis, Essex, Kniskern, O.Narhi, Lee, Jang, and Takahashi. This is not a proper basis for an obviousness rejection.

Since the cited references fail to disclose each and every element as currently claimed and there is no suggestion or motivation for combining all the references of record, the claimed invention is both novel and nonobvious. Accordingly, the rejection of Claims 14-15 under 35 U.S.C. § 103(a) has been overcome.

For these and the other reasons stated above, it is submitted that Claims 14 – 15 are patentable over the references, and it is respectfully submitted that the rejections under 35 U.S.C. §112 and §103(a) have been overcome.

#### Conclusion

In view of the amendments and remarks made above, Applicant submits that the pending Claims are now in condition for allowance. Applicant respectfully requests that the claims be allowed to issue. If the Examiner wishes to discuss the application or the comments herein, the Examiner is urged to contact the undersigned by telephone.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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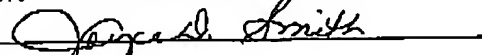
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CLT01/4777503v1

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Joyce E. Smith

Date: April 20, 2006